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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,049	03/02/2002	Chi Yung Fu		3263

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Chi Yung Fu  
1005 Duncan Street  
San Francisco, CA 94131

EXAMINER

BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/087,049

Applicant(s)

FU, CHI YUNG

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-30 is/are pending in the application.
- 4a) Of the above claim(s) 9, 17-19, 21, 22 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 10-16, 20 and 23-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This application has been reassigned to a new examiner.
2. The amendment submitted 15 July 2005 after final rejection has been entered in full.
3. The finality of the Office action mailed 16 June 2005 is withdrawn.
4. This Office action contains new grounds of rejection not necessitated by the Applicant's amendments and therefore is a non-final Office action.

### ***Election/Restrictions***

5. Upon review of the election by the Applicant in the paper filed 21 August 2003, the election of an entity subspecies of *S. aureus* entity is incompatible with the election of an entity species of human. Therefore the entity election will be considered to be the species of human. Claim 30 is drawn to unelected marker species that are produced by entities incompatible with the elected human entity species, and is therefore withdrawn. The previously elected medical condition of diabetes and marker species of acetone will also be examined. Claim 9 is withdrawn as it is limited to a nonelected food entity. The specification states on page 6 that lipid peroxidation can be measured by analysis of ethane and pentane, and claims 17 and claims 18, 19, and 21 which depend from claim 17 drawn to analysis of membrane deterioration are withdrawn as drawn to an unelected marker species. It is brought to the applicant's attention that if claims 18 and 21 were amended to depend from claim 11, claims 18 and 21 would be rejoined as reading on the elected acetone marker species. Claim 22 is drawn to an unelected marker species and is withdrawn. Claim 29 is drawn to a type of apparatus of claim 23 and is rejoined.

### ***Claim Rejections - 35 USC § 102***

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6. The rejection of claims 1-4, 6-8, 10-12, 14, 23, 24, and 30 under 35 U.S.C. 102(a) as being clearly anticipated by Pavlou et al. (2000) in the Office action mailed 16 June 2005 is withdrawn in view of the amendment and arguments filed 15 July 2005.

***Claim Rejections - 35 USC § 103***

7. The rejection of claims 1-4, 6-8, 10-12, 14, 16, 17, 21, 22-24, 27, and 30 under 35 U.S.C. 103(a) as being unpatentable over Pavlou et al. (2000) taken with Phillips (US 6,221,026 B1) in the Office action mailed 16 June 2005 is withdrawn in view of the amendment and arguments filed 15 July 2005.

8. The rejection of claims 1-4, 6-8, 10-12, 14, 16-24, 27, and 30 under 35 U.S.C. 103(a) as being unpatentable over Pavlou et al. (2000) taken with Phillips (US 6,221,026 B1) in view of Matteucci et al. (2000), and Kanety et al. (1994) is withdrawn in view of the amendment and arguments filed 15 July 2005.

9. The rejection of claims 23, 24, and 26-28 under 35 U.S.C. 103(a) as being unpatentable over Pavlou et al. (2000) taken with Phillips (US 6,221,026 B1) in view of Lewis (US006170318B1) is withdrawn in view of the amendment and arguments filed 15 July 2005.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 1, 3, 4, 6-8, 10-13, 16, 20, 23-25, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ping et al. (1997) in view of Ping et al. (1996).

The claims are drawn to a method of detecting acetone in the breath of a patient to diagnose diabetes. The method utilizes an electronic nose and processes the data with an artificial neural network (ANN) and a fuzzy filter. In some embodiments the data processing is adapted to the source of the sample. In some embodiments the acetone levels are correlated to other markers of diabetes. In some embodiments the claims are drawn to a apparatus that performs the method, and the apparatus contains heaters linked to a sensor array.

Ping et al. (1997) shows a method of using an electronic nose to diagnose diabetes by detection of acetone in the breath of patients. Ping et al. (1997) shows on page 1032, column 2 that their device uses ANN pattern recognition and a fuzzy cluster pattern recognition. Ping et al. (1997) shows in figures 1-3 and page 1033 that their electronic nose has heaters operably linked to the detector array. Ping et al. (1997) shows in the first column of page 1033 and throughout that their method trains the apparatus to distinguish sample response patterns of normal patients and patients with diabetes. Ping et al. correlates acetone and blood glucose levels in patients in

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Table 1 and figure 7. Ping et al. (1997) does not explicitly describe processing of the data with ANN and fuzzy filters.

Ping et al. (1996) describes an electronic nose that analyzes odor molecules by use of ANN combined with fuzzy logic. Ping et al. (1996) describes a two-layer ANN on page 1701, and learning algorithms using ANN and fuzzy logic to choose input clusters on pages 1708 and 1709. Ping et al. (1996) shows on pages 1709-1711 that their method allows for discrimination of different odor molecules in samples, including acetone.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method and apparatus of Ping et al. (1997) by use of the ANN and fuzzy logic method of Ping et al. (1996) because Ping et al. (1997) refer to the method of Ping et al. (1996) in their bibliography, and Ping et al. (1996) shows that their method allows for discrimination of different molecules in gas samples.

13. Claims 1, 2, 11, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ping et al. (1997) in view of Ping et al. (1996) as applied to claims 1, 3, 4, 6-8, 10-13, 16, 20, 23-25, 27, and 28 above, and further in view of Phillips (US Patent No. 6,221,026).

The claims are drawn to a method of detecting acetone in the breath of a patient to diagnose diabetes. The method utilizes an electronic nose and processes the data by correction for environmental levels of the examined compound and for endogenous levels in the patient of the examined compound from the environment.

Ping et al. (1997) in view of Ping et al. (1996) as applied to claims 1, 3, 4, 6-8, 10-13, 16, 20, 23-25, 27, and 28 above does not show correction for environmental contribution to acetone levels in patient breath samples.

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Phillips shows methods of assaying breath of patients for organic compounds. Phillips shows in column 2, lines 36-40, column 6, lines 62-64, column 11-14, and figure 4 that environmental contributions to assayed organic compounds produced by a patient in breath samples should be controlled for. Phillips shows detection of acetone in breath in column 12, line 51.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Ping et al. (1997) in view of Ping et al. (1996) as applied to claims 1, 3, 4, 6-8, 10-13, 16, 20, 23-25, 27, and 28 above by use of the methods of correction for environmental contributions for assayed compounds because Phillips shows that such corrections are needed to determine the level of an assayed component that is produced by the patient.

14. Claims 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ping et al. (1997) in view of Ping et al. (1996) as applied to claims 1, 3, 4, 6-8, 10-13, 16, 20, 23-25, 27, and 28 above, and further in view of Lewis (US Patent No. 6,170,318).

The claims are drawn to an apparatus for detecting acetone in the breath of a patient to diagnose diabetes. The apparatus comprises an electronic nose operably linked to a microwave oven.

Ping et al. (1997) in view of Ping et al. (1996) as applied to claims 1, 3, 4, 6-8, 10-13, 16, 20, 23-25, 27, and 28 above does not show an electronic nose operably linked to a microwave oven.

Lewis shows throughout electronic noses adapted for a variety of applications. Lewis shows an electronic nose linked to a microwave oven in figure 19, column 15, lines 37-40,

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column 17, line 59 through column 18 line 15 for the purpose of analysis of food cooked in the microwave oven.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of Ping et al. (1997) in view of Ping et al. (1996) as applied to claims 1, 3, 4, 6-8, 10-13, 16, 20, 23-25, 27, and 28 above by linking a microwave oven because Lewis shows that such an apparatus is useful to analyze food cooked in the oven.

15. Claims 23 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ping et al. (1997) in view of Ping et al. (1996) as applied to claims 1, 3, 4, 6-8, 10-13, 16, 20, 23-25, 27, and 28 above, and further in view of Sun et al.

The claims are drawn to an apparatus for detecting acetone in the breath of a patient to diagnose diabetes. The apparatus uses an ANN with at least 4 layers.

Ping et al. (1997) in view of Ping et al. (1996) as applied to claims 1, 3, 4, 6-8, 10-13, 16, 20, 23-25, 27, and 28 above does not show an electronic nose that uses an ANN with at least 4 layers.

Sun et al. describes the use of ANN and fuzzy logic to detect features in a system. Sun et al. shows in the abstract and throughout that multiple layers in the ANN may be used. Sun et al. shows the general applicability of their method in column 5, lines 50-61, and use of fuzzy filtering in column 16, lines 48-59.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of Ping et al. (1997) in view of Ping et al. (1996) as applied to claims 1, 3, 4, 6-8, 10-13, 16, 20, 23-25, 27, and 28 above by use of ANN of multiple



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layers because Sun et al. shows that ANN with multiple layers may be used to detect features in a system.

### ***Conclusion***

16. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD. can be reached on 571 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 5 August 2005  
John S. Brusca  
Primary Examiner  
Art Unit 1631

jsb